GV Health	**TITLE:**	**Clinical Trial Standard Operating Procedure 08: Case Report Forms and Source Documents**	
Document Type:	Procedure	**Approved by:**	Research Management and Governance Committee
Directorate:	CMO + Medical Services	**Section:**	Research
Author/Prepared by:	Dr Ainsley Robinson	**Position:**	Clinical Trials Coordinator

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1. PURPOSE:

To describe the procedures related to the completion of electronic and paper-based Case Report Forms (CRF), and maintenance of Source Documents to ensure compliance with the International Council for Harmonisation of Technical requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice (and requirements of the Integrated Addendum to this Guideline published by the Therapeutics Goods Administration (TGA)) (ICH GCP E6 (R2)) and relevant local GV Health policies, procedures, and frameworks.

2. SCOPE:

This Standard Operating Procedure (SOPs) applies to all GV Health employees, visiting health professionals, contractors, any external researchers, consultants, and volunteers who propose to undertake, administrate, review and/or govern human research involving GV Health patients/participants, facilities and/or staff. All study personnel involved in the clinical study must operate within their scope of practice.

3. PROCEDURE:

3.1. Completion of Case Report Forms:

Where electronic medical records (EMR) are used, a validation system is required with an inbuilt correction and audit trail feature. In the case where there is no inbuilt validated audit trail, printed records of the changes and corrections (e.g., data queries) must be retained.

3.1.1. The Investigator must:

- Ensure the accuracy, completeness, legibility (including any changes or corrections), and timeliness of Source Data and data recording adheres to the Protocol and monitoring plan requirements, and also the Supervision Plan.
- Ensure that any party delegated to perform data entry or signing for data completeness is recorded on the Delegation Log and is trained to perform those trial-related duties and functions.
- Ensure that changes to the paper Source Document do not obscure the original entry, are traceable (signed and dated) and explained (i.e., an audit trail should be maintained).

Source Data are defined as: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

Collection of accurate Source Data (contained in Source Documents) is essential for compliance with ICH GCP E6 (R2). The format used (whether paper or electronic) should permit the reconstruction of the clinical care given to the participant and describe any significant participant-related events that may occur during the conduct of the trial.

Source Data should be attributable, legible, contemporaneous, original, and accurate (ALCOA+). Changes to Source Data should be traceable, should not obscure the original entry, and should be

explained if necessary. In addition, Source Data in electronic Form should be complete, consistent, enduring, and available (ALCOA+).

The CRF is defined in ICH GCP E6 (R2) as: A printed, optical or electronic document designed to record all of the Protocol required information to be reported to the Sponsor on each trial subject. The data collected in the CRF is used as the basis of the trial report and any publications, as well as making up part of the data for regulatory approval for the unapproved therapeutic goods. The Principal Investigator (PI) has ultimate responsibility for the content of the CRF but may delegate the task to suitably qualified individuals. The PI should, however, maintain oversight of the quality of the data provided to the Sponsor.

Access to the participant's trial related information should be limited to authorised users. Where access (e.g. for trial monitors, auditors and inspectors) cannot be limited to trial participants, certified paper copies of trial related information should be printed.

3.2. Source Documents:

3.2.1. The Investigator must:

- Maintain adequate Source Documents and trial records including all key observations on each of the trial participants.
- Store all trial-related documents in a Study Master File (SMF)/Satellite Site Study File (SSSF) as required by the applicable regulatory requirement, Sponsor and Protocol and take measures to prevent accidental or premature destruction of these documents.
- Ensure, for both paper and electronic documents, all changes, corrections, and amendments are tracked, and version dates and numbers, are updated to reflect the changed data and to maintain the integrity of the data. An explanation of the changes is noted in a record of change.
- Ensure all staff are aware that, upon request, direct access to all trial related records is given to the monitor, auditor, Human Research Ethics Committee (HREC), Research Governance Officer (RGO) or regulatory authority, to enable Source Data verification, Sponsor audits or regulatory inspection. Direct access is stipulated in the Clinical Trial Research Agreement (CTRA) and outlined to the participant via the Participant Information and Consent Form (PICF).
- Ensure that for telehealth consultations, the call is documented in the participant's health and medical record at each site as documented in the Supervision Plan which will detail where the original and certified copies are stored. The written record will include a brief summary of the Protocol number, consultation, follow up instructions and that the visit was conducted via telehealth.
- For paper records, ensure that the agreed approach to Source Documents in the Supervision Plan is followed. This could include requiring a certified copy of any key Essential Documentation generated at the Satellite Site is sent to the Primary Site for filing in the SMF e.g. serious adverse events

(SAEs) reports, to allow remote monitoring by Sponsor and for auditing and inspection purposes. These can be sent via email or post.

- Where EMR are in use, ensure that access to the patient's trial related information is limited to authorised users only. The Investigator must ensure appropriate controls are in place to allow access to the patient's/participant's EMR for the purpose of monitoring the study. Authorised users should include Contract Research Associates (CRAs), auditors and regulatory inspectors, subject to those users meeting local access requirements.
- Where there is not a locally accepted practice to limit access in the EMR to limited patients/participants, other measures must be put in place to ensure the patient's/participant's privacy and confidentiality are respected e.g. print the trial related information, sign as a certified copy and place in a paper record for access by Sponsor, regulatory inspectors, and auditors etc.
- For teletrials, providing access to the Satellite Site EMR from the Primary Site (for PI oversight and study monitoring) is to be encouraged in order to increase the efficiency of study conduct under the Teletrial Model.

ABBREVIATIONS AND TERMS:
Please refer to GVH_CT-SOP-Abbreviations and Terms.

KEY LEGISLATION, ACTS & STANDARDS:
National Safety and Quality Health Service (NSQHS) Standards:

- Standard 1 Clinical Governance

KEY ALIGNED DOCUMENTS:
Nil.

REFERENCES:

National Clinical Trials Governance Framework and User Guide, Australian Commission on Safety and Quality in Health Care. (2022). Safetyandquality.gov.au. https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide

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